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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/263,626 03/05/99 MOORE

P PF466

EXAMINER

HM12/0103

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ART UNIT

PAPER NUMBER

1646  
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01/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/263,626

Applicant(s)

P.A. Moore et al.

Examiner  
Michael Brannock, Ph.D.

Group Art Unit  
1646



☒ Responsive to communication(s) filed on Oct 18, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

- ☒ Claim(s) 11, 13, 17-21, and 23-59 is/are pending in the application.
- Of the above, claim(s) 11, 13, 17-21, 23, and 24 is/are withdrawn from consideration.
- ☒ Claim(s) 41 is/are allowed.
- ☒ Claim(s) 25-40 and 42-59 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Status of Application: Amendments and Claims*

Regarding Applicant's response in Paper NO: 5, dated 10/18/1999, Applicant is notified of the following:

1. Applicant's election with traverse of Group I, claims 1-10, 14, 15 and 22 is acknowledged and made of record.
2. Claims 1-10, 12, 14-16 and 22 have been canceled and claims 25-59 have been entered in full; furthermore, claims 25-29 are considered by the examiner to directed to the elected Group I.
3. Claims 11, 13, 17-21, and 23- 25-59 are pending in the instant application.
4. Claims 11, 13, 17-21, and 23-59 are subject to restriction.
5. Applicant's traversal of the restriction requirement set forth in Paper NO: 3 (10/01/99) is on the grounds that a search of Groups I-X would not be a serious burden on the examiner. This is not found persuasive for the following reasons:

Under MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 8702.01, 806.04, 808.01) or distinct as claimed (see MPEP § 806.05- §806.05(I)); and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a)- 806.04(I), § 808.01(a), and § 808.02).

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Consistent with current patent practice, a serious search burden may be established by (A) separate classification thereof; (B) a separate status in the art when they are classifiable together; (C) a different field of search. These criteria were met in the above restriction. Further, a search is directed not only to art which would be anticipatory, but also to art that would render the invention obvious. Thus, the ten groups require divergent searches, and to search all ten inventions would be burdensome. Therefore, the restriction is maintained and made final.

Claims 11, 13, 17-21, and 23-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper NO: 5, dated 10/18/1999.

***Priority***

6. The instant application claims priority to U.S. Provisional Application 60/078563, filed March 19, 1998 and to U.S. Provisional Application 60/086505, filed May 22, 1998, however no basis for priority is found in US 60/078563 for SEQ ID NO: 1 and 2 nor for ATCC deposit number 209691. Priority for SEQ ID NO: 1 and 2 and for ATCC deposit number 209691 is found in U.S. Provisional Application 60/086505, filed May 22, 1998

***Specification***

7. The disclosure is objected to because of the following informalities: The purpose and/or the relevance of the table on pages 115-119 is unclear. Further, the table should be labeled to an extent sufficient to make the reader aware of the intended purpose of the table.

Appropriate correction is required.

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*Claim Rejections - 35 USC § 112*

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37(a) recites a polynucleotide encoding a polypeptide comprising amino acids m-371, wherein m is an integer. It is unclear whether applicant intends the term "m-371" to designate a range, i.e. from integer m *to* 371, or if the applicant intends the term to designate an arithmetic expression, i.e. integer m *minus* 371. This ambiguity is also true for 37(b) and (c) and for claims 38-40 which depend on claim 37. For the purpose of examination in this Office Action the terms will be assumed to designate a range; however, appropriate clarification is required.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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11. Claims 25-34, 37-40, 42-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids that hybridize to the endogenous nucleic acid encoding a polypeptide of SEQ ID NO: 2 under stringent conditions (stringent conditions as defined on page 4, lines 23-30), does not reasonably provide enablement for nucleic acids that do not hybridize under the above conditions nor for nucleic acids contained in ATCC Deposit NOS: 209641 and 209641.

Claims 25-36 recite nucleic acids contained in ATCC Deposit NOS: 209641 and 209641. The instant specification puts forth that "a representative clone containing *all or most* of the sequence of SEQ ID NO: 1 was deposited with the American Type Culture Collection on March 23, 1998, and was given the ATCC Deposit Number 209691. A second clone was deposited with the ATCC on February 25, 1998, and given ATCC Deposit Number 209641" (see page 4, lines 15-19). The specification has failed to provide enabling basis for the claimed invention for the following reasons:

a) If *most* of the sequence of SEQ ID NO: 1, but not *all* of the sequence, is contained in ATCC Deposit Number 209691, then in order to use the claimed invention, one of skill in the art would need to know which sequences of SEQ ID NO: 1 were present in ATCC Deposit Number 209691 and which sequences were not present.

b) The instant application has failed to provide guidance as to the nature, function, or identity of ATCC Deposit Number 20964, nor of the relationship, if any, between SEQ ID NO: 1

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and ATCC Deposit Number 20964. One of skill in the art would, therefore, be unable to use the claimed invention.

c) The specification recites tissue specific expression of a polypeptide of SEQ ID NO: 2 (see page 7, L15-24 and page 8, L21-33), therefore a double stranded nucleic acid encoding a polypeptide of SEQ ID NO: 2 could reasonably be expected to be useful as a tissue specific marker. However, the specification has not provided guidance as to which nucleic acids encoding the almost infinite number amino acid substitutions recited in claims 25 and 34 nor which nucleic acids encoding a polypeptide of SEQ ID NO: 2 but which differ from SEQ ID NO: 1 due to the redundancy of the genetic code would be useful as a tissue specific probe.

Therefore, due to the large quantity of experimentation necessary to determine which nucleic acid molecules encoding a polypeptide of SEQ ID NO: 2 which are different than that of SEQ ID NO: 1 and are also suitable for use as a tissue specific marker (as discussed above), and to the unpredictability as to which nucleic acids might produce a tissue specific expression pattern that was identical to that produced by SEQ ID NO: 1, and due to the absence of working examples of the these nucleotides, and to the large scope of the claims which encompass thousands of different nucleic acids wherein the specification provides guidance as to the use of only SEQ ID NO: 1, undue experimentation would be required of the skilled artisan to make and use the invention commensurate with the claims applicant is seeking protection for.

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12. Claims 51-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 51 recites a polynucleotide encoding a polypeptide of SEQ ID NO: 2 named Cytokine Receptor Common Gamma Chain Like (CRCGCL) wherein the polypeptide regulates the differentiation and or proliferation of cells. The specification discloses that CRCGCL shares homology with members of the cytokine receptor family (see page 1, lines 8-9) and that binding of a cytokine to members of this family stimulates certain and often independent signal transduction pathways (lines 19-20); and also, that members of this family regulate a variety of cellular process, including activation, proliferation, and differentiation (lines 21-23) of such cell types as T and B lymphocytes, natural killer cells, macrophages and monocytes (lines 26-28).

The specification also provides guidance to one skilled in the art to try various experiments through which the activity (if any) of CRCGCL on specific cell types might then be determined (e.g. see Examples 15, 16 and 17: pages 90-94). These suggested experiments, however, provide the skilled artisan with only a starting point for further research and investigation. The specification has failed to teach one of skill in the art which cell types to use, if any can be used, to regulate cell differentiation and/or proliferation with CRCGCL. Furthermore, if certain cell types can be regulated with the claimed invention, then the specification has not provided guidance as to the nature of the regulation, e.g. the specification has not taught whether to use CRCGCL to promote or to inhibit cell differentiation and/or



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proliferation. Furthermore, the specification puts forth that the closest homolog of CRCGCL is the Interleukin-2 receptor gamma (see page 2, lines 27-29). R.E. Callard and A.J.H. Gearing (The Cytokine FactsBook, Academic Press, London 1994) teach that the IL-2 receptor gamma does not bind cytokine directly, but works in conjunction with IL-2 receptor alpha and or beta subunits (see page 41, line 4). The specification asserts that CRCGCL binds to cytokines but does not provide evidence to support the assertion, therefore, absent evidence to the contrary, CRCGCL (alone) would not be expected to regulate the differentiation and/or proliferation of cells as is required by claims 51-59.

Therefore due to the large quantity of experimentation necessary to determine which cell types, if any could be used with the claimed invention and then to determine the nature of the regulation of the cells that are to be used, the absence of working examples wherein CRCGCL is used to regulate cell proliferation and/or differentiation, the complex nature of the art - e.g. R.E. Callard and A.J.H. Gearing (supra) teach that IL-2 receptor regulation occurs through multifaceted protein/protein interactions, undue experimentation would be required of the skilled artisan to use the claimed invention, if in fact it can be used as claimed.

Additionally, claims 51-59 ATCC Deposit NOS: 209641 and 209641. Such is also not enabled for the reasons set forth above in item 11.

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Therefore due to the large quantity of experimentation necessary to determine which cell types, if any could be used with the claimed invention and then to determine the nature of the regulation of the cells that are to be used, the absence of working examples wherein CRCGCL is used to regulate cell proliferation and/or differentiation, the complex nature of the art - e.g. R.E. Callard and A.J.H. Gearing (supra) teach that IL-2 receptor regulation occurs through multifaceted protein/protein interactions, undue experimentation would be required of the skilled artisan to use the claimed invention, if in fact it can be used as claimed.

Additionally, claims 51-59 recite ATCC Deposit NOS: 209641 and 209641. Such is also not enabled for the reasons set forth above in item 11.

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***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by GenEmbl accession number X91553. Claims 36-38 claim a nucleic acid that hybridizes to a polynucleotide of SEQ ID NO: 1 (claim 36) or encoding a polypeptide comprising at least one amino acid residue of SEQ ID NO: 2 (claims 37c and 38). GenEmbl accession number X91553 discloses a polynucleotide that is 100% identical to SEQ ID NO: 1 over the range of positions 778-806, and would therefore hybridize to SEQ ID NO: 1 under highly stringent conditions and would also be expected to encode a polypeptide having a sequence identical to positions 256-264 of SEQ ID NO: 2.

***Allowable Subject Matter***

15. Claim 41 is allowable.

***Conclusions***

16. Claims 1-10, 12, 14-16 and 22 are canceled.

17. Claims 11, 13, 17-21, and 23-24 are withdrawn from consideration.

18. Claims 25-40, 42-59 are rejected.

19. Claim 41 is allowable.

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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.21.

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER

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*MB*

December 30, 1999